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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,635	10/07/2003	Hans-Georg Ihlenfeldt	BMID9967CUS	5091

23690 7590 05/15/2007
ROCHE DIAGNOSTICS OPERATIONS INC.
9115 Hague Road
Indianapolis, IN 46250-0457

EXAMINER	
KIM, ALEXANDER D	
ART UNIT	**PAPER NUMBER**
1656	
MAIL DATE	**DELIVERY MODE**
05/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/680,635	**Applicant(s)** IHLENFELDT ET AL.	
	Examiner Alexander D. Kim	**Art Unit** 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-20, 22-27 and 29* is/are rejected.

7)☒ Claim(s) *21 and 28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Dictionary recombinant, Blast 2 sequences results, SEQ Alignment.

DETAILED ACTION

Application Status

1. In response to the previous Office actions, a non-Final rejection (mailed on 10/11/2006), Applicants filed a response and amendment received on 02/12/2007. Said amendment amended claims 15-16, 21-22, canceled claims 1-14; and added claims 27-29. Thus, claims 15-29 are pending in this instant case.

Withdrawn-Objections to the Specification

2. The previous objection of the Title is withdrawn by the virtue of Applicants' amendment.

3. The previous objection of Abstract is withdrawn by the virtue of Applicants' amendment.

4. The previous objection of the ribose sugar drawing on page 1 is withdrawn by the virtue of Applicants' argument.

5. The previous objection of the citation disclosed in p. 9 line 8, without the author name is withdrawn by the virtue of Applicants' amendment.

New-Claim Objections

6. Claims 21 and 28 is objected because it depends from the rejected claim.

Maintained-Claim Rejections - 35 USC § 112

7. The previous rejection of Claims 15-20, 22-27 and 29 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicants amended the claims to a recombinant *Drosophila melanogaster* kinase and argue the claim 15 which is limited to a recombinant *Drosophila melanogaster* kinase are "commensurate with the disclosure provided by applicants" and overcome an instant written description rejection.

The amended claims has a scope which is limited to *Drosophila melanogaster* kinase. However, the claims still encompass any kinase which uses all natural deoxynucleoside from a *Drosophila melanogaster.* As noted in the previous Non-Final office action, the instant specification and the prior art cannot describe the structure of a very broad claimed genus and one skilled in the art would not be in possession of the claimed genus. The claim 27 is broad to encompass any kinase having as small as two consecutive amino acids from the polypeptide encoded by the SEQ ID NO: 1. The claim 29 encompasses any deoxynucleoside kinase from any source. For the reasons above, the instant rejection is maintained.

8. The previous rejection of Claims 15-20, 22-27 and 29 under 35 U.S.C. 112, first paragraph, scope of enablement, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicants argue adding limitation of *Drosophila melanogster* into the claim to clarify what is encompassed by the claims, and argue the scope of the claims are enabled, and Applicants allege the claims are enabled since Examiner has recognized Dm-dNK is enabled as if the scope of *Drosophila melanogster* kinase and the scope of Dm-dNK is identical, or Dm-dNK can represent any *Drosophila melanogster* kinase sufficiently. Applicants complete argument is acknowledged and has been carefully considered, however, is not persuasive for the following reasons.

The amended claims continue to encompass any kinase in and/or from Drosophila melanogaster, wherein the kinase is characterized by: accepting all natural deoxynucleosides and stable during the synthesis of nucleoside monophosphate in the absence of stabilizing SH agent and protein.

It is noted the Dm-dNK is prior art recognized the *Drosophila melanogaster* deoxyribonucleoside kinase (emphasis added, see Munch-Petersen et al. and Johansson et al.) consisting of the amino acid sequence shown in page 23816 of Johansson et al., which is a species encompassed by a genus that is any kinase (vary widely varying genus) as recited in the claims. As noted in previous office action, it is unpredictable for any kinase in and/or from *Drosophila melanogaster* with said characterization stated above. The claim 27 is broad to encompass any kinase having as small as two consecutive amino acids from the polypeptide encoded by the SEQ ID NO: 1. The claim 29 encompasses any deoxynucleoside kinase from any source. For the reasons above, the instant rejection is maintained.

Withdrawn-Claim Rejections - 35 USC § 102

9. The previous rejection of Claims 15-26 under 35 U.S.C. 102(a) as being anticipated by reference by Johansson et al. (1999, August 20, The Journal of biological Chemistry, Vol. 274, p. 23814-23819) is withdrawn by the virtue of Applicants' filing of certified translation of German application 198 46 838.5 filed on 10/12/1998.

Maintained-Claim Rejections - 35 USC § 102

10. The previous rejection of Claims 15-20, 22-27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by reference by Munch-Petersen et al. (1998, February 13, The Journal of biological Chemistry, Vol. 273, p. 3926-3931) and evidenced by Johansson et al. (1999, August 20, The Journal of biological Chemistry, Vol. 274, p. 23814-23819) is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicants acknowledge Munch-Petersen et al. disclose a Drosophila melanogster kinase but this kinase "cannot be considered to be "recombinant" as that term is commonly understood" (see bottom of p. 7 in Remarks) by citing Wikipedia encyclopedia from the internet. However, the term recombinant is also defined as "a genetic material from gene splicing" (see Encarta Dictionary in the Attachment). Thus, the cell of Munch-Petersen et al. undergoing splicing and translating the kinase is considered as the recombinant kinase. Applicants also argue that the kinase of Munch-Petersen et al. must have some other structural differences compared to the instant kinase because of the difference in remaining activity after incubation in "50 mM Tris pH

7.5 and 2.5 mM MgCl2 solution at 37°C for up to 50 minutes" (see middle of p. 8, Remarks). Applicants argue the native kinase of Munch-Petersen et al. fails to anticipate the highly stable recombinant kinase of the present invention; thus, "there must be some other structural differences between these two kinases" (see middle of p. 8, Remarks). However, the claim does not require the stable activity. As it is written, the claims only require the kinase to be stable during catalysis. The less activity shown by the wild type kinase from the native cell by Munch-Petersen et al. meets all claim limitations of being stable during catalysis under the condition in Claim 15 as shown in Figure 7, as cited by the Applicants. The amended claim recites "90% of its activity" for the limitation. This limitation is met by the kinase of Munch-Petersen et al. because claim 16 encompasses any activity, immunogenic, for example. The kinase of Munch-Petersen et al. has a sequence which meets the disclosed limitation of Claim 27. As described above, the instant claims are broad to encompass the kinase of Munch-Petersen et al.; thus, instant claims are anticipated by the Munch-Petersen et al. For the reasons above, the instant rejection is maintained.

Withdrawn-Claim Rejections - 35 USC § 102/103

11. The previous rejection of Claims 15-26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Munch-Petersen et al. (1998, February 13, The Journal of biological Chemistry, Vol. 273, p. 3926-3931) and Johansson et al. (1999, August 20, The Journal of biological Chemistry, Vol. 274, p. 23814-23819) is withdrawn by the virtue of Applicants arguments.

Additional Note

12. The SEQ ID NO: 1 contains nucleic acid designated as "r" in the position 308, which needs to be clarified if this is a typographical error.

Summary of Pending Issues

13. The following is a summary of the issues pending in the instant application:

   a. Claims 21 and 28 are objected because it depends from the rejected claim.
   b. The previous rejection of Claims 15-20, 22-27 and 29 under 35 U.S.C. § 112, first paragraph, written description, is maintained.
   c. The previous rejection of Claims 15-20, 22-27 and 29 under 35 U.S.C. 112, first paragraph, scope of enablement, is maintained.
   d. The previous rejection of Claims 15-20, 22-27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by reference by Munch-Petersen et al. and evidenced by Johansson et al. is maintained.

Conclusion

14. Claims 15-29 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered section in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander D. Kim whose telephone number is (571) 272-5266. The examiner can normally be reached on 8AM-5PM.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alexander Kim
April 30, 2007

RICHARD HUTSON, PH.D.
PRIMARY EXAMINER

Seq Alignment

10681635

```
RESULT 1
E49662
LOCUS       E49662                   753 bp    DNA     linear   PAT 05-NOV-2005
DEFINITION  Insect cell-derived deoxynucleoside kinase for synthetic of
            nucleotide monophosphoric acid.
ACCESSION   E49662
VERSION     E49662.1  GI:18628131
KEYWORDS    JP 2000139481-A/1.
SOURCE      Drosophila melanogaster (fruit fly)
  ORGANISM  Drosophila melanogaster
            Eukaryota; Metazoa; Arthropoda; Hexapoda; Insecta; Pterygota;
            Neoptera; Endopterygota; Diptera; Brachycera; Muscomorpha;
            Ephydroidea; Drosophilidae; Drosophila.
REFERENCE   1  (bases 1 to 753)
  AUTHORS   Irenferuto,H.J., Petersen,B.M., Pisukuru,J. and Sondaga,L.
  TITLE     Insect cell-derived deoxynucleoside kinase for synthetic of
            nucleotide monophosphoric acid
  JOURNAL   Patent: JP 2000139481-A 1 23-MAY-2000;
            ROCHE DIAGNOSTICS GMBH
COMMENT     OS   Drosophila melanogaster
            PN   JP 2000139481-A/1
            PD   23-MAY-2000
            PF   12-OCT-1999 JP 1999290285
            PR   12-OCT-1998 DE   19846838:5,31-MAR-1999 DE   19914644:6 PI
            HANS JORUKU IRENFERUTO,BRIGITTE MUNCH PETERSEN,JURU PISUKURU, PI
            LEIF SONDAGATO
            PC   C12N15/09,C12N9/12//(C12N9/12,C12R1:19),C12N15/00 CC
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            FT                   /organism='Drosophila melanogaster'.
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ORIGIN

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  Matches  753;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 ATGGCGGAGGCAGCATCCTGTGCCCGAAAGGGGACCAAGTACGCCGAGGGCACCCAGCCC 60
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Qy         61 TTCACCGTCCTCATCGAGGGCAACATCGGCAGCGGGAAGACCACGTATTTGAACCACTTC 120
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Qy        121 GAGAAGTACAAGAACGACATTTGCCTGCTGACCGAGCCCGTCGAGAAGTGGCGCAACGTC 180
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Qy        181 AACGGGGTAAATCTGCTGGAGCTGATGTACAAAGATCCCAAGAAGTGGGCCATGCCCTTT 240
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Qy        241 CAGAGTTATGTCACGCTGACCATGCTGCAGTCGCACACCGCCCCAACCAACAAGAAGCTA 300
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Qy      301 AAAATAARGGAGCGCTCCATTTTTAGCGCTCGCTATTGCTTCGTGGAGAACATGCGACGA 360
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Db      301 AAAATAARGGAGCGCTCCATTTTTAGCGCTCGCTATTGCTTCGTGGAGAACATGCGACGA 360

Qy      361 AACGGCTCGCTGGAGCAGGGCATGTACAATACGCTGGAGGAGTGGTACAAGTTCATCGAA 420
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Qy      421 GAGTCCATTCACCTGCAGGCGGACCTCATCATATATCTGCGCACCTCGCCGGAGGTGGCG 480
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Qy      541 CAGGAGCTGCATGAGTTGCACCAGGACTGGTTGATACACCAGAGACGACCGCAGTCGTGC 600
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Qy      601 AAGGTCCTAGTCCTCGATGCCGATCTGAACCTGGAAAACATTGGCACCGAGTACCAGCGC 660
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Qy      661 TCGGAGAGCAGCATATTCGACGCCATCTCAAGTAACCAACAGCCCTCGCCGGTTCGTGTG 720
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RESULT 2
AF045610
LOCUS       AF045610                1121 bp    mRNA    linear   INV 24-FEB-2000
DEFINITION  Drosophila melanogaster deoxyribonucleoside kinase (Dm-dNK) mRNA,
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ACCESSION   AF045610
VERSION     AF045610.2  GI:7025918
KEYWORDS    .
SOURCE      Drosophila melanogaster (fruit fly)
  ORGANISM  Drosophila melanogaster
            Eukaryota; Metazoa; Arthropoda; Hexapoda; Insecta; Pterygota;
            Neoptera; Endopterygota; Diptera; Brachycera; Muscomorpha;
            Ephydroidea; Drosophilidae; Drosophila.
REFERENCE   1  (bases 1 to 1121)
  AUTHORS   Johansson,M., van Rompay,A.R., Degreve,B., Balzarini,J. and
            Karlsson,A.
  TITLE     Cloning and characterization of the multisubstrate
            deoxyribonucleoside kinase of Drosophila melanogaster
  JOURNAL   J. Biol. Chem. 274 (34), 23814-23819 (1999)
   PUBMED   10446143
REFERENCE   2  (bases 1 to 1121)
  AUTHORS   Johansson,M. and Karlsson,A.
  TITLE     Direct Submission
  JOURNAL   Submitted (02-FEB-1998) Clinical Virology, Karolinska Institute,
            Huddinge Hospital, Stockholm S-141 86, Sweden
REFERENCE   3  (bases 1 to 1121)
  AUTHORS   Johansson,M. and Karlsson,A.
  TITLE     Direct Submission
  JOURNAL   Submitted (24-FEB-2000) Clinical Virology, Karolinska Institute,
            Huddinge Hospital, Stockholm S-141 86, Sweden
  REMARK    Sequence update by submitter
COMMENT     On Feb 24, 2000 this sequence version replaced gi:5708379.
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                     Drosophila EST project clone LD15983"
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     CDS             125. .877
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ORIGIN

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Qy          1 ATGGCGGAGGCAGCATCCTGTGCCCGAAAGGGGACCAAGTACGCCGAGGGCACCCAGCCC 60
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Qy         61 TTCACCGTCCTCATCGAGGGCAACATCGGCAGCGGGAAGACCACGTATTTGAACCACTTC 120
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Qy        181 AACGGGGTAAATCTGCTGGAGCTGATGTACAAAGATCCCAAGAAGTGGGCCATGCCCTTT 240
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Qy        241 CAGAGTTATGTCACGCTGACCATGCTGCAGTCGCACACCGCCCCAACCAACAAGAAGCTA 300
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Qy        421 GAGTCCATTCACCTGCAGGCGGACCTCATCATATATCTGCGCACCTCGCCGGAGGTGGCG 480
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Qy     541 CAGGAGCTGCATGAGTTGCACCAGGACTGGTTGATACACCAGAGACGACCGCAGTCGTGC 600
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Qy     601 AAGGTCCTAGTCCTCGATGCCGATCTGAACCTGGAAAACATTGGCACCGAGTACCAGCGC 660
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Qy     661 TCGGAGAGCAGCATATTCGACGCCATCTCAAGTAACCAACAGCCCTCGCCGGTTCGTGTG 720
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Qy     721 TCGCCCAGCAAGCGCCAGAGGGTCGCCAGATAA 753
           |||||||||||||||||||||||||||||||||
Db     845 TCGCCCAGCAAGCGCCAGAGGGTCGCCAGATAA 877
```

```
RESULT 2
AF045610
LOCUS       AF045610                1121 bp    mRNA    linear   INV 24-FEB-2000
DEFINITION  Drosophila melanogaster deoxyribonucleoside kinase (Dm-dNK) mRNA,
            complete cds.
ACCESSION   AF045610
VERSION     AF045610.2  GI:7025918
KEYWORDS    .
SOURCE      Drosophila melanogaster (fruit fly)
  ORGANISM  Drosophila melanogaster
            Eukaryota; Metazoa; Arthropoda; Hexapoda; Insecta; Pterygota;
            Neoptera; Endopterygota; Diptera; Brachycera; Muscomorpha;
            Ephydroidea; Drosophilidae; Drosophila.
REFERENCE   1  (bases 1 to 1121)
  AUTHORS   Johansson,M., van Rompay,A.R., Degreve,B., Balzarini,J. and
            Karlsson,A.
  TITLE     Cloning and characterization of the multisubstrate
            deoxyribonucleoside kinase of Drosophila melanogaster
  JOURNAL   J. Biol. Chem. 274 (34), 23814-23819 (1999)
   PUBMED   10446143
REFERENCE   2  (bases 1 to 1121)
  AUTHORS   Johansson,M. and Karlsson,A.
  TITLE     Direct Submission
  JOURNAL   Submitted (02-FEB-1998) Clinical Virology, Karolinska Institute,
            Huddinge Hospital, Stockholm S-141 86, Sweden
REFERENCE   3  (bases 1 to 1121)
  AUTHORS   Johansson,M. and Karlsson,A.
  TITLE     Direct Submission
  JOURNAL   Submitted (24-FEB-2000) Clinical Virology, Karolinska Institute,
            Huddinge Hospital, Stockholm S-141 86, Sweden
  REMARK    Sequence update by submitter
COMMENT     On Feb 24, 2000 this sequence version replaced gi:5708379.
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ORIGIN

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Qy          1 ATGGCGGAGGCAGCATCCTGTGCCCGAAAGGGGACCAAGTACGCCGAGGGCACCCAGCCC 60
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